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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,187

05/21/2007

Woo Heon Song

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

BROWE, DAVID

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

09/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,187	Applicant(s) SONG ET AL.	
	Examiner DAVID M. BROWE	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>June 2, 2006 and August 30, 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6 are pending.

Foreign Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the Republic of Korea on February 14, 2005. It is noted, however, that applicant has not filed a certified copy of the 10-2005-0012104 application as required by 35 U.S.C. 119(b).

Domestic Benefit

Applicant's claim for the benefit of prior-filed application PCT/KR06/00459, filed February 8, 2006, under 35 U.S.C. 365(a) is acknowledged.

Abstract

The abstract of the disclosure is objected to for the following reasons:

a) the abstract should be limited to a single paragraph within the range of 50-150 words. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "This invention relates to," etc.

b) Since the invention relates to a method of manufacture, the abstract should include the steps.

Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen *et al.* (U.S. Patent No. 6,602,522).

Applicant Claims

Applicants claim an oral pharmaceutical formulation comprising: a) an enteric coating, and b) a core containing pantoprazole or its alkaline metal salts. The enteric coating comprises an enteric polymer, such as methacrylic acid copolymer, and polyethylene glycol as a plasticizer. The core, in addition to pantoprazole or its alkaline

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metal salts, further comprises a low-viscosity hydroxypropylmethyl cellulose as a binder, lactose as a filler/diluent, and crospovidone as a disintegrant.

Applicants also claim a method of manufacturing an oral pharmaceutical formulation which includes the steps of: a) forming a core comprising pantoprazole or its alkaline metal salts, b) dissolving or suspending the enteric polymer, such as methacrylic acid copolymer, and polyethylene glycol in a solvent, and c) spraying the enteric suspension on the core. The core may further contain a low-viscosity hydroxypropylmethylcellulose, lactose, and crospovidone.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Chen *et al.* disclose an oral pharmaceutical formulation comprising: a) an enteric coating, and b) a core containing pantoprazole or its alkaline metal salts (Col. 2, Ins. 1-20, 57-64). An intermediate layer is not present between the enteric coating and the core (Col. 1, Ins. 48-50; Col. 2, Ins. 39-43). The enteric coating comprises an enteric polymer, such as methacrylic acid copolymer (Col. 3, Ins. 48-60), and polyethylene glycol as a plasticizer (Col. 4, Ins. 9, 13). The core, in addition to pantoprazole or its alkaline metal salts, further comprises a low-viscosity hydroxypropylmethyl cellulose as a binder (Col. 3, Ins. 19-24), lactose as a filler/diluent (Col. 3, Ins. 34-35), and crospovidone as a disintegrant (Col. 3, Ins. 40-43).

Chen *et al.* also disclose a method of manufacturing an oral pharmaceutical formulation which includes the steps of: a) forming a core comprising pantoprazole or its alkaline metal salts, b) dissolving or suspending the enteric polymer, such as methacrylic acid copolymer, and polyethylene glycol in a solvent, and c) spraying the

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enteric suspension on the core. The core may further contain a low-viscosity hydroxypropylmethylcellulose, lactose, and croscopovidone (Col. 4, Ins. 20-33; Col. 5, Ins. 49-52).

It is noted here for the record that Chebli (U.S. Patent Application Pub. No. 20050266075) also discloses the same oral pharmaceutical formulation comprising: a) an enteric coating, and b) a core containing pantoprazole or its alkaline metal salts, with no intermediate layer between the enteric coating and the core; and a method of manufacturing said oral pharmaceutical formulation.

Ascertainment of the Difference Between the Scope of the Prior Art and the Claims (MPEP §2141.012)

Chen et al. disclose an oral pharmaceutical formulation containing an acid-labile substituted benzimidazole including omeprazole, lansoprazole, pantoprazole, perpaprazole or a pharmaceutically acceptable salt thereof. Examples provided incorporate omeprazole into the core of the formulation. Applicants specifically incorporate pantoprazole in their formulation.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious for one of ordinary skill in the art at the time of the present invention to produce an oral pharmaceutical formulation comprising: a) an enteric coating, and b) a core containing pantoprazole or its alkaline metal salts. Since Chen *et al.* have disclosed a formulation consisting of an enteric coating and a core, in which an acid-labile substituted benzimidazole, particularly the proton pump

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inhibitor omeprazole, contained in the core remains stable without the need for an intermediate layer, one of ordinary skill in the art would be motivated to make the same formulation with pantoprazole, another pharmaceutically useful acid-labile substituted benzimidazole in the market as a proton pump inhibitor, with the reasonable expectation of success that the pantoprazole will remain stable with no need for an intermediate layer. Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID M. BROWNE whose telephone number is 571-270-1320. The examiner can normally be reached on Monday-Friday 7:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID M. BROWE
Patent Examiner, Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616